Docket No.: 246472007600
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Patent Application of:
Arnold KELLER

Application No.: 10/530,211 Confirmation No.: 9918

Filed: April 4, 2005 Art Unit: 3774

For: HIP PROSTHESIS INCLUDING A SHAFT TO BE INSERTED INTO THE FEMUR Examiner: Suba Ganesan

APPEAL BRIEF

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This brief is filed in furtherance of the Notice of Appeal filed on September 1, 2010.

I. REAL PARTY IN INTEREST

The real party in interest for this appeal is Waldemar Link GmbH & Co. KG., Hamburg, Germany.

II. RELATED APPEALS, INTERFERENCES, AND JUDICIAL PROCEEDINGS

There are no appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS

Claims 1-8 stand finally rejected and are the subject of this appeal.

IV. STATUS OF AMENDMENTS

No amendment has been filed subsequently to the May 21, 2010 final Office Action from which this appeal is taken. Accordingly, the claims on appeal stand as amended in the November 4, 2009 Amendment.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Claim 1 is the only independent claim on appeal. Claim 1 recites a hip prosthesis (p. 4, l. 22; Abstract) configured for cementless implantation (p. 1, l. 37 – p. 2, l. 2) comprising a shaft configured to be inserted into a femur (element 1 of FIG. 1; p. 4, l. 22 and ll. 31-33) and a femoral neck extending medially relative to an implanted position of the prosthesis in the femur (element 2 of FIG. 1; p. 4, l. 22). The shaft has a proximal part configured to be inserted in a metaphyseal region of the femur (element 6 of FIG. 1; p. 4, ll. 24-31) and a distal part configured to be inserted into a diaphyseal region of the femur (element 7 of FIG. 1; p. 4, ll. 24-26; p. 5, ll. 13-15). The proximal part comprises fins that project from front and rear faces of the proximal part (element 8 of FIGS. 1-4; p. 4, ll. 24-31; p. 5, ll. 25-26). Each fin extends from a distal end of the proximal part (an area near element 9 of FIG. 1; p. 5, ll. 38-39) to a proximal end of the proximal part (an area near element 26 of FIG. 1; p. 6, ll. 1-3) and has a steep medial flank oriented in a medial direction relative to the implanted position (element 23 of FIGS. 3-4; p. 5, ll. 26-27). The steep medial flank encloses an angle between 5° and 15° with respect to a longitudinal axis of the shaft (p. 3, ll. 12-15; p. 6, ll. 3-6). The width of the fins increases from the distal end to the proximal end of the proximal part (p. 5, l. 38 – p. 6, l. 3) and the height of the fins decreases in a lateral direction, relative to the implanted position and perpendicular to the longitudinal axis of the shaft, from the medial edge (p. 6, ll. 23-25). The distal part comprises diaphyseal anchoring projections (p. 5, ll. 13-20).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 1-8 were properly rejected under 35 USC 103(a) on Niederer (US 4,359,785) in view of Tanamal (US 5,755,811) and Itoman (US 6,190,417).

VII. ARGUMENT

The rejection of claim 1 for obviousness over Niederer in view of Tanamal and Itoman should be reversed because the combination fails to teach all of the claimed limitations and because one of ordinary skill in the art would not combine the references as suggested by the Examiner. The rejection of claims 2-8 should be reversed due to their dependency on claim 1.

A. None of the cited references discloses or suggests fins having a steep medial flank enclosing an angle between 5° and 15° with respect to a longitudinal axis of the shaft.

The Examiner relies on Niederer's collar-like projection 12 to teach the claimed fins having a steep medial flank enclosing an angle between 5° and 15° with respect to a longitudinal axis of the shaft. Office Action dated May 21, 2010, p. 4. But Niederer's collar-like projection 12 is disclosed as being *substantially aligned* with neck 6 of Niederer's prosthesis, which has an orientation of *about 45° to 50°* with respect to a longitudinal axis of shank 2. This is evident from FIG. 1 and several passages of Niederer:

> "The projection extends at least approximately in the direction of the neck relative to the shank" (col. 2, ll. 8-9);
>
> "...the collar-like projection extends at least approximately in alignment with the lower edge of the neck of the prosthesis" (col. 2, ll. 22-24); and
>
> "...a collar-like projection 12 is disposed between the shank 2 and the neck 6 and extends at least approximately in the direction of the neck 6 relative to the shank 2" (column 2, lines 63-66).

The orientation of neck 6 of Niederer's prosthesis, as is typical with hip prostheseses, corresponds substantially to that of the neck of the natural femur and lies somewhere in the range of about 45° to 50°. See Niederer, FIG. 1; also see Tanamal, FIG. 1 and Itoman, FIG. 1. Consequently, Niederer's collar-like projection 12 encloses an angle of about 45° to 50° relative

to the longitudinal axis of the prosthesis. Niederer thus does not disclose or suggest fins having a steep medial flank enclosing an angle between 5° and 15° with respect to a longitudinal axis of the shaft, as claimed, and in effect dissuades persons of ordinary skill in the art from employing fins with such a steep medial flank.

In prior Actions, the Examiner has contended that Niederer discloses that collar-like projection 12 encloses *some* acute angle relative to the longitudinal axis, rather than an angle within the range of about 45° to 50°. For example, the Examiner has stated the following:

> "The language 'at least approximately in the direction of the neck' is sufficiently broad to encompass a range of 5-15 degrees. 'At least approximately' implies that the fin can be slightly biased towards the neck; Examiner contends that this statement from Niederer is NOT evidence in favor of only large angles (such as the approximately 50 degree angle shown in the figures of Niederer), but is rather a broad suggestion to an ordinary practitioner in the art." (Office Action dated August 4, 2009, page 2)

The Examiner ignores the express teachings of Niederer in making this argument. Niederer discloses two functions for collar-like projection 12. First, collar-like projection 12 is supposed to prevent shank 2 from sinking into the bone cement under vertical loads:

> "As such, the collar is additionally supported on the edge of the cement quiver within the bone and prevents the shank from sinking into the bone cement" (col. 1, ll. 35-38); and

> "Moreover - as is the case with a collar of a conventional prosthesis - good support of the prosthesis in the cement is made possible" (col. 2, ll. 17-19).

This function of projection 12 is even evident in its name: a *collar-like* projection. Second, while collar-like projection 12 would probably be most effective in preventing shank 2 from sinking into the cement if it were to enclose an angle of about 90° relative to the longitudinal axis, that would ignore Niederer's second purpose for the projection. Niederer's second intended function for collar-like projection 12 is to be effective against loads on joint head 11:

> "...due to the torque effect of the force acting on the joint head, the danger exists that deformations of the shank blades may occur. This danger is counteracted in that the collar type projection forming the transition between the shank and the prosthesis neck extends in a direction parallel to the prosthesis neck" (Abstract); and

> "Regardless of where the pivot point for the torque occurring due to the eccentric load must be assumed on the collar 12, a secure anchoring of the shank in the cement and bone bearing is thereby obtained." (col. 3, ll. 10-14).

According to Niederer, these two functions are achieved by substantially aligning collar-like projection 12 with neck 6 of the prosthesis.

Niederer's disclosure regarding the angle of collar-like projection 12 is thus not just some random, indeterminate disclosure with little technical consequence, as the Examiner appears to assume. Rather, substantially aligning the projection with the prosthesis's neck achieves the precise technical effects Niederer set out to achieve with its prosthesis configuration. If the projection of Niederer had an angle of only 15° with the longitudinal axis it would have very little effect against the prosthesis sinking into bone cement. Furthermore, such an angle would bring the collar out of line with the neck and would thus reduce the collar's ability to mitigate loads from the joint head. Accordingly, one of ordinary skill in the art would not interpret Niederer's disclosure of "at least approximately in the direction of the neck" as disclosing or suggesting an angle of 5° to 15°.

In an additional line of argumentation, the Examiner contends that modifying Niederer's collar-like projection 12 to have an angle within the range of 5° to 15° would have been an obvious design choice to one of ordinary skill in the art because it would involve a mere change in size of a component. Office Action dated May 21, 2010, p. 4. With all due respect, this is a *non sequitur*. Changing the size of collar-like projection 12 would not in any way alter its angle of orientation with respect to neck 6 of the prosthesis. Accordingly, one of ordinary skill in the art could not achieve fins having a steep medial flank enclosing an angle between 5° and 15°, as claimed, merely by changing the size of Niederer's collar-like projection 12.

The Examiner also argues that "the specific angle of the angled fin of Niederer would have been readily apparent and obvious in view of numerous design considerations for hip prosthesis." Office Action dated May 21, 2010, p. 4. The salient issue, of course, is whether the *claimed* angle of the fins would have been obvious to one of ordinary skill in the art. But

Niederer teaches away from fins having a steep medial flank enclosing an angle between 5° and 15°, as claimed, since the angle of collar-like projection 12 has to be well above 15° in order to achieve the projection's functions of preventing shank 2 from sinking into the bone cement under vertical loads and absorbing loads on the joint head to prevent deformations of shank 2. Concomitantly, changing the angle of collar-like projection 12 as suggested by the Examiner would render Niederer's prosthesis unsatisfactory for its intended purpose since the prosthesis would be more likely to sink into the bone cement under vertical loads and would not be able to counteract the danger of deformations of the shank blade. Consequently, one of ordinary skill in the art would not have modified the angle of Niederer's collar-like projection as suggested by the Examiner.

In view of the above, Niederer does not disclose or suggest fins having a steep medial flank enclosing an angle between 5° and 15° with respect to a longitudinal axis of the shaft, as claimed. The other cited art also fails to disclose or suggest the claimed fins. Therefore, the rejection of claim 1 for obviousness over Niederer in view of Tanamal and Itoman should be reversed.

B. One of ordinary skill in the art would not have combined Niederer and Tanamal as suggested by the Examiner.

Claim 1 recites a hip prosthesis configured for cementless implantation. The Examiner concedes that Niederer is directed to a hip prosthesis adapted for implantation *with cement*. To remedy Niederer's deficiency, the Examiner relies on Tanamal, which discloses cementless implantation (col. 3, ll. 51-57) and teaches the use of fins to "cut into the bone and become embedded into the cancellous bone" (col. 3, ll. 57-65).

As explained on pages 1 and 2 of appellant's specification, a hip prosthesis anchored by bone cement raises different concerns than a prosthesis adapted for cementless implantation. When implanting a hip prosthesis with bone cement, the shaft of the prosthesis and the bone cement are inserted into the medullary cavity of the bone. Since the space between the surface of

the prosthesis and the bone material is completely filled with bone cement, and since the bone cement adheres well to the surface of the prosthesis and the bone material, force transmission is evenly distributed over the surface of the prosthesis and a stable anchoring is achieved.

In contrast, when a prosthesis is implanted without bone cement the anchoring is provided by ingrowth of bone material into the surface of the prosthesis. Under these circumstances it can be much more difficult to obtain a good anchoring and an even distribution of force transmission. Furthermore, the bone material in the methaphyseal portion has different properties than the bone material in the diaphyseal portion, which means that the different portions of the surface of the prosthesis need to be specifically adapted. One of ordinary skill in the art would be aware of these differences between cemented implantation and cementless implantation.

The Examiner does not provide a cogent reason why one of ordinary skill in the art would have modified Niederer's cement-implantation prosthesis to implement cementless implantation as taught by Tanamal. The Examiner contends that "it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the prosthetic with a cement-less implantation as taught by Tanamal for the purpose of providing a direct press fit with native cancellous bone." Office Action dated May 21, 2010, p. 4. This is circular logic. Direct press fitting with native cancellous bone is simply a characteristic of Tanamal's cementless implantation. This characteristic is irrelevant to Niederer's cement-implantation prosthesis since, by design, the prosthesis implants into the bone with the aid of bone cement. The Examiner is essentially stating that it would have been obvious to modify Niederer to implement cementless implantation to achieve the effect of implanting the prosthesis without cement (i.e., direct press fit with native cancellous bone). The Examiner does not provide any reasons why such a direct press fit is preferable over Niederer's cemented implantation, much less a cogent reason why one of ordinary skill in the art would have endeavored to completely

change Niederer's selected implantation method. Furthermore, the use of cement appears to be an essential component of Niederer's configuration for achieving the object of reducing the risk of deformation of the shank 2. See Niederer, col. 3, ll. 3-15.

In view of the above, one of ordinary skill in the art would not have had any reason to modify Niederer to implement cementless implantation as taught by Tanamal. Therefore, the rejection of claim 1 for obviousness over Niederer in view of Tanamal and Itoman should be reversed.

VIII. CONCLUSION

For at least the foregoing reasons, Appellant respectfully requests reversal of the obviousness rejections of claims 1-8.

Dated: October 28, 2010

Respectfully submitted,

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CLAIMS APPENDIX

1. A hip prosthesis configured for cementless implantation comprising a shaft configured to be inserted into a femur and a femoral neck extending medially relative to an implanted position of the prosthesis in the femur, the shaft having a proximal part configured to be inserted in a metaphyseal region of the femur and a distal part configured to be inserted into a diaphyseal region of the femur, the proximal part comprising fins that project from front and rear faces of the proximal part, each fin extending from a distal end of the proximal part to a proximal end of the proximal part and having a steep medial flank oriented in a medial direction relative to the implanted position, the steep medial flank enclosing an angle between 5° and 15° with respect to a longitudinal axis of the shaft, the width of the fins increasing from the distal end to the proximal end of the proximal part, the height of the fins decreasing in a lateral direction, relative to the implanted position and perpendicular to the longitudinal axis of the shaft, from the medial edge, the distal part comprising diaphyseal anchoring projections.

2. The prosthesis as claimed in claim 1, wherein the fins extend rectilinearly.

3. The prosthesis as claimed in claim 1 or 2, wherein the height of the fins above the surface of the shaft increases from the distal end to the proximal end of the proximal part.

4. The prosthesis as claimed in claim 1 or 2, wherein the height of the lateral edge of the fins is not greater than half the height of the medial edge.

5. The prosthesis as claimed in claim 1 or 2, further comprising a device for anchoring the endoprosthesis to a diaphysis.

6. The prosthesis as claimed in claim 3, wherein the height of the lateral edge of the fins is not greater than half the height of the medial edge.

7. The prosthesis as claimed in claim 3, further comprising a device for anchoring the endoprosthesis to a diaphysis.

8. The prosthesis as claimed in claim 4, further comprising a device for anchoring the endoprosthesis to a diaphysis.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.